Biotester

The *Biotester* is a compact instrument, designed to help Biomedical engineers test medical equipment. The *Biotester's* main features are:

- ECG simulation any rate from 10BPM to 240BPM
- IBP simulation any rate from 10BPM to 240BPM
- Respiration simulation 0.1Ohms to 10.0Ohms
- Stimulator tester testing stimulators and TENS units
- Flow/Pressure tester testing infusion devices

SRI

Biotester

Version 1.12

Copyright, April, 2003

ECG/IBP/Respiration Simulator
Stimulator Meter
Flow & Pressure Tester

Stirling Rock International
19 Meluca Crescent
Hornsby Heights
NSW 2077
Australia
Tel. 612 9482 5898
www.sr-i.com

7032

The manufacturer assumes no responsibility for the use of this product in a medical environment or any incidents that may occur from the use of this product.

The manufacturer reserves the right to update the hardware, software and documentation at any time without notice.

Thank you to the Biomedical Engineers, technicians and hospital staff who have been involved in this project.

CONTENTS

1.0 Quick Guide
2.0 Introduction
3.0 Operation
4.0 ECG simulation
5.0 IBP (Invasive Blood Pressure) simulation
6.0 Programmable User waveform
7.0 Stimulator tester
8.0 Flow/Pressure tester
9.0 Memory variables
10.0 Respiration simulation
11.0 Operator ID
12.0 Display Backlight
13.0 Specifications
14.0 Trouble shooting

Appendix A - connector pinouts
Appendix B - waveform tables

1.0 Quick Guide

Main Menu

1 ECG	1-type	ECG➡Pace➡Pulse➡Triangle ➡Sin
	2-rate	30 ➡ 60 ➡ 120 ➡ 240 BPM
		or 1 ➡ 10 ➡ 50 ➡ 60 Hz
	3-size	½mV ➡ 1mV ➡ 2mV
	5- Save	Parameters saved (to power-on default)
	6-Recall	Parameters reset (to power-on default)
	7-rate+	Increment the heart rate
	8-rate-	Decrement the heart rate
	0-light	
	#-advance help	(show the next help message)
2 IBP	1-type	IBP ➡ IBPzero ➡Pulse➡Triangle➡Sin
	....	other keys same as ECG
3 User	3-size	Half ➡ Normal ➡ Double
		quit
4 Stimulator		quit
5 Flow/Pressure		1 - save last reading and reset Flow tester
		save - mmHg ➡ kPa ➡ psi
6 Memory		Memory address? (Enter no. from 0-127)
		0: 12 5234 (Enter new value)
7 Resp	2-rate	10 ➡ 20 ➡ 30 ➡ 60 BPM
	3- size	0.1➡0.2➡0.5➡... ➡10.0Ω
9 Operator ID		Enter new operator ID and press #
0-light		(turn the backlight on or off)
#-advance help		(show the next help message on line2)

2.0 INTRODUCTION

The *Biotester* is a compact instrument, designed to help Biomedical Engineers test medical equipment. The *Biotester's* main features are:

ECG simulation	any rate from 10BPM to 240BPM
IBP simulation	" " " " "
Respiration simulation	0.1Ohms to 10.0Ohms
Stimulator tester	testing stimulators and TENS units
Flow/Pressure tester	testing infusion pumps

3.0 OPERATION

To run the unit, install a PP3 size 9V battery into the battery compartment. Ensure that the battery is wedged in the compartment properly to ensure there is no movement or "rattling".

Now activate the unit by pressing the on/off switch on the side of the unit. The LCD will activate and display "Biotester v1.xx" where 1.xx is the software version. The second line is the operator ID line *(please see Section 11.0 for a detailed explanation)*. This display and the display backlight will be on for 2 seconds, and then "Main Menu" will be displayed. The second line is the help line and will show the available functions. This help line will change automatically every 5 seconds. (*Refer to the Quick Guide on page 1 for a summary of the functions accessible from the keypad).*

4.0 ECG Simulation

Press the "1" key from the Main Menu to access this mode.

In this mode, the ECG waveform parameters are displayed and can be changed. The second line displays the help line, but will not change automatically. Press the # key to change the help line.The ECG waveform is updated every 1ms, and the normal sinus rhythm is composed of 500 samples. The ECG type, rate and size are displayed on the LCD screen - these values are configurable by the operator. The heart symbol will flash during the QRS complex.

The backlight may be activated or deactivated on pressing the 0 button.

4.1 ECG Waveform

The ECG waveform may be changed by pressing the "1" key:

ECG	Standard ECG waveform
Pace	Standard ECG waveform with a 2 ms spike before the P wave
Pulse	200ms Pulse
Triangle	Triangle waveform (1Hz, 10Hz, 50Hz and 60Hz)
Sin	Sinusoidal waveform (1Hz, 10Hz, 50Hz, and 60Hz)

4.2 ECG RATE

The ECG rate is changed by pressing the "2" key. The possible values are 30, 60, 120 and 240 BPM (beats per minute). The ECG rate may also be incremented or decremented by pressing the "7" key or the "8" key - *see sections 1.7 and 1.8.* If the ECG type is Triangle or Sin, the rate will be displayed as a frequency - 1Hz, 10Hz, 50Hz and 60Hz. The maximum Pulse waveform rate is 120BPM.

4.3 ECG SIZE

The ECG size is changed by pressing the "3" key. The possible ECG sizes are 1/2mV, 1mV and 2mV. This size is referenced to the LEAD II on an ECG monitor.

4.5 SAVE PARAMETERS

To save the current parameters to memory, press the "5" key. When the *Biotester* is next turned on, the ECG will be set to these parameters.

4.6 RECALL PARAMETERS

To reload the ECG power-on settings, press the "6" key. This feature is useful for checking that the correct parameters have been saved, and for changing multiple parameters on a waveform with one key press.

4.7 RATE INCREMENT

Press the "7" key to increment the patient heart rate. This function is active in the ECG, Pace and Pulse waveform types. The ECG rate can be incremented to a maximum of 240 BPM. By holding down the "7" key for more than a second, the rate will automatically keep incrementing.

4.8 RATE DECREMENT

Press the "8" key to decrement the patient heart rate. This function is active in the ECG, Pace and Pulse waveform types. The ECG rate can be decremented to 10BPM. By holding down the "8" key for more than one second, the rate will automatically keep decrementing.

5.0 IBP Simulation

In this mode, the Invasive Blood Pressure waveform parameters are displayed and can be changed.

The IBP waveform is available on the D9 connector above the display - *see Appendix A for pinouts*. Static blood pressure testing is not available on the *Biotester*. The IBP waveform (wfm), rate and size are displayed on the LCD screen - these values are configurable by the operator. The heart symbol will flash on during the QRS segments.

The backlight may be turned on/off by pressing the "0" key. The help may be changed by pressing #.

5.1 IBP Waveform

The IBP waveform may be changed by pressing the "1" key. At present, there are 5 waveforms accessible. The waveform types are:

IBP	Standard IBP waveform
IBPzero	Used to zero the transducer
Pulse	200ms Pulse
Triangle	Triangle waveform (1, 10, 50, & 60Hz)
Sin	Sinusoidal waveform (1,10,50,& 60Hz)

5.2 IBP RATE

The IBP rate may be changed by pressing the "2" key. The possible values are 30, 60, 120 and 240 BPM. The IBP rate may also be incremented or decremented by pressing the "7" or the "8" key - *see section 2.7 and 2.8 for more information.* If the IBP type is Triangle or Sin, the rate will be displayed as a frequency. 1, 10, 50 and 60Hz are the possible frequencies for these waveforms.

5.3 IBP SIZE

The IBP size can be changed by pressing the "3" key. The symbol displayed on the right hand side of the top line, will reflect the current size selected as standard, double or half.

5.5 PARAMETERS SAVE

To save the current parameters to memory, press the "5" key. The display will show "Parameters saved". The next time the *Biotester* is turned on, these parameters will be loaded from memory.

5.6 PARAMETERS RECALL

To set the IBP to the default power on settings, press the "6" key.

5.7 RATE INCREMENT

Press the "7" key to increment the patient heart rate. This function is active in the IBP and Pulse waveform types. The IBP rate can be incremented to 240BPM. By holding down the "7" key for more than one second, the rate will automatically keep incrementing.

5.8 RATE DECREMENT

Press the "8" key to decrement the patient heart rate. This function is active in the IBP and Pulse waveform types. The IBP rate can be decremented to 10BPM. By holding down the "8" key for more than one second, the rate will automatically keep decrementing.

6.0 USER WAVEFORM

The USER waveform is a unique feature of the *Biotester* which allows any waveform to be programmed into the *Biotester*. The waveform rate cannot be adjusted, but the size may be set to normal, half or double.

The waveform is reconfigured in the Memory variables section of the program - *see section 8.0*. The waveforms are stored in the following way:

Memory address 64 - User baseline value (0-255)
Memory addresses 65-95 - User waveform data

The baseline value is the first value output (0=0V, 255 = 5V). The waveform data is then read and the waveform is output until a 0 is read. At this stage, the waveform output is set to the baseline value and the process restarts.

The waveform is output as straight-line sections, and curves are approximated by several straight-line segments.

7.0 STIMULATOR TESTER

The stimulator tester will measure the output amplitude and rate of nerve muscle stimulators and TENS machines. The stimulator tester will measure to an amplitude range of 100mA +-1mA and a rate of 65000ms +- 1ms (for a pulse width greater than 200us). The load applied is 1KOhm.

Plug in the stimulator adaptor to the 9 pin connector near the display. Press the "4" key from the Main Menu. Every pulse will be measured and displayed. If no pulses are sensed after 8s, the screen will show .0mA ——ms. This allows pulses to be captured on the screen for 8s. To quit out of this mode, hold the quit button. The other buttons are not used.

The display will show the amplitude reading in mA and rate in ms:

Stim
34.5mA . 498ms

The stimulator calibration may be modified if the reading is inaccurate - *see section 9.0 Memory Variables for more information*. The mA reading accuracy is +-0.4mA.

If very short pulses are measured, the stimulator mA reading may vary slightly.

8.0 FLOW/PRESSURE TESTER

The Flow/Pressure tester is a unique function in the *Biotester* which allows the Biomedical Engineer to test Infusion and other constant flow pumps during routine service. The *Biotester* is the only known handheld flow meter designed for biomedical equipment.

8.1 FLOW TEST

The flow test is a single-shot test. This means the flow-rate can only be measured once and cannot be measured continuously. The volume cannot be measured with the *Biotester*. The flow test has been designed as a quick but accurate single test for infusion pumps.

To measure flow rate, ensure that there is no fluid in the *Biotester* from the previous test. Stand the *Biotester* up using the rear tilt bar or simply hold the *Biotester* in a semi-vertical position. Now connect the lower flow connector to the infusion pump, using a luer lock fitting.

Press the "5" key from the Main Menu. The display should now show:

```
Flow ———
  0mmHg          .0
```

Run the infusion pump. There are two fluid sensors inside the *Biotester* - a start sensor and a stop sensor. When the fluid reaches the start sensor, the display will show:

```
Flow  1secs
  0mmHg   .0
```

The time will increase until the fluid reaches the second fluid sensor. When the fluid reaches the second sensor, the display will show the flow reading in ml/Hr

Flow 94.5ml/Hr
0mmHg .0

To perform another test, empty the *Biotester* of fluid and press the "1" key. The display will now resemble:

Flow ———
0mmHg 94.5

Note that the last flow reading is saved on the right hand side of line 2 for later reference. The Flow Test Calibration is stored in the Memory Variables and can be altered by the user for better accuracy if needed - *see section 9.0 for more information*. The *Biotester* accuracy is +-2% of the reading. This accuracy also depends on the infusion pump flow - jerky flows will be slightly more inaccurate.

8.2 PRESSURE TESTER

The Pressure tester will measure the pressure from 0 to 15psi. The pressure can be displayed in mmHg, kPa or psi with mmHg being the default setting. Connect the pressure hose to the luer connector in the middle of the right hand side of the *Biotester*. Apply pressure and the Pressure tester will automatically display the pressure on the display in real-time.

The pressure will be displayed as mmHg. To change the units, press the "save" key. The other units are kPa and psi.

The Pressure Calibration is stored in the Memory Variables and can be altered if for better accuracy if needed - *see section 9.0 for more information.*

9.0 MEMORY VARIABLES

The Memory Variables section allows the user to alter stored parameters for their own use. 128 numbers are stored in the Memory Variables section, and each can be accessed individually. Several numbers are joined together to form integers for calibration purposes (16 bit numbers). Below is a table of the 128 Memory Variables and their associated function.

Memory Variable	Typical Value	Function and Description
0-15	Name Tel	Operator ID (16 characters)
16	5	Backlight on time (seconds)
17,18,19,20	0,60,1,1	ECG type,rate,size(0=1/2mV),rate1
21	5	Pressure Zero Calibration
22,23	1450	Pressure Span Calibration
24,25	650	Flow Tester Calibration
26	30	Auto Power-Off timer (minutes)
27,28	950	Stimulator mA calibration
29	8	Stimulator offset in ADC counts
40	ml/Hr	Flow Units (to 7 characters)
48	VFib	User Waveform Name (to 8 chars)
64	20	User baseline
65-127		User waveform

To access or change a Memory Variable, press the "8" key from the Main Menu. The display will show:

Memory Address?

Enter the number of the Memory variable to access and press the "3" key. The display will now show (for example):

Memory 16bit
1: 33 20001

The first number (1) followed by the colon is the number or address of Memory Variable being accessed. The second number (33) is the value of this Memory Variable. The third number (20001) is the combined value of this Memory variable and the next Memory Variable.

9.1 Backlight Time

This is the length of time in seconds the backlight will stay on for. If this is set to 5, the backlight will stay on for 5 seconds when the "0" key is pressed (This function has not been implemented in Version 1.09)

9.2 ECG Type, Rate, Size, Rate1

These Memory variables are the values which are stored or recalled from Memory when the "5" or "6" kerbs are pressed in ECG mode - *see section 4.5*. The rate1 values are used in Triangle or Sin mode (0=1Hz, 1=10Hz, 2= 50Hz, 3=60Hz).

9.3 Pressure Zero and Span Calibration

The Pressure Zero if the amplifier offset value. The Pressure Span is a 16 bit number, and is directly proportional to the pressure value.

9.4 Flow Calibration

The Flow Calibration is a 16bit number and is directly proportional to the displayed flow rate.

9.5 Auto-Power Off Time

This is the length of time in minutes after the last key press before the unit will automatically turn off. After setting this value, turn the *Biotester* off and on to reinitialise the Auto Power-Off timer.

9.6 Stimulator Calibration, and Offset

The Stimulator Calibration is a 16bit number and is directly proportional to the mA displayed.

9.7 Flow Units

The flow units are stored in Memory as a character string of up to 7 characters. Enter the characters in ASCII decimal format. The string must be terminated with a 0.

9.8 User Waveform Name

The User waveform name is stored in Memory as a character string of up to 7 characters. Enter the characters in ASCII decimal format. The string must be terminated with a 0.

9.9 User Waveform

One waveform may be programmed into Memory. The first number is the baseline and this is the reference point from

which the waveform starts. After the baseline the waveform data is read and output during the User waveform - *see section 6.0*. The waveform data is stored as straight line segments, with each line segment consisting of three memory variables:

Memory variable 1:	period of segment in ms
Memory variable 2,3:	gradient (-32767 to 32767)

To test this function, program the waveform in Appendix B into the User waveform. This is the standard ECG wave. Then alter parts of the waveform and view the altered ECG waveform.

10.0 RESPIRATION

The respiration function changes the resistance across the RArm and LArm connectors to simulate an expiring and inspiring chest. A pair of lung symbols are displayed on the screen during inspiration (when the resistance is increasing). The waveform changes linearly with time, and the respiration will be displayed as a triangle wave on a patient monitor.

The backlight may be activated or deactivated on pressing the "0" key.

The second line help may be scrolled by pressing # (or save) key.

10.2 RESPIRATION RATE

The respiration rate may be changed by pressing the "2"key. This rate is independent of the heart rate. The possible values are:

10 ➡ 20 ➡ 30 ➡ 60 BPM

10.3 RESPIRATION AMPLITUDE

The amplitude of the resistance variation may be changed by pressing the "3" key. The possible values are:

0.1Ω ➡ 0.2Ω ➡ 0.5Ω ➡ 1.0Ω ➡ 2.5Ω ➡ 5.0Ω ➡ 10.0Ω

Ω is the symbol for Ohms, the unit of resistance.

11.0 OPERATOR ID

This function allows the operator to enter a name and contact number into the first 16 Memory variable values. Whenever the *Biotester* is turned on, the Operator ID line is displayed on the second line of the display for 2 seconds. The method used to alter the line is similar to the method used in mobile phones - each key corresponds to 8 characters:

Keypad key	1	1,A,B,C,a,b,c,d
	2	2,D,E,F,d,e,f,g
	3	3,G,H,I,g,h,i,j
	4	4,J,K,L,j,k,l,m
	5	5,M,N,O,m,n,o,p
	6	6,P,Q,R,p,q,r,s
	7	7,S,T,U,s,t,u,v
	8	8,V,W,X,v,w,x,y
	9	9,Y,Z,[,y,z,{,|
	0	0,SPACE,!,",@,A,B,C
	*	Escape
	#	Save character and move to the next character

11.1 DISPLAY BACKLIGHT

In all menus, the display backlight may be turned on or off by pressing the "0" key. The backlight will automatically turn off after a set number of seconds to save battery power - *see section 9.1*. The backlight time is typically set to 10 seconds. (Not implemented in Version1.09)

12.0 SPECIFICATIONS

Biotester Version 1.xx

Power Supply	Internal 9V battery
Battery current	10mA typically, 60mA with backlight
Battery life	20 hours typically
ECG amplitude	1/2mV, 1mV or 2mV (+/-0.1mV) 0-5V referenced to Lead II 10BPM to 600BPM (+/-1BPM) 100 - 500 Ohms between leads ECG, Pacemaker,Sin,Triangle,Pulse,User
IBP	10BPM to 240BPM
Respiration	0.1Ω to 10.0Ω RArm to LArm 10,20,30,60 BPM +- 1BPM
Stimulator (1 channel)	Reading from 2mA to 100mA (+-0.4mA accuracy) Stimulator period in ms +-1ms
Flow Tester	0.1ml/Hr to 999.9ml/Hr (+-2% accuracy)
Pressure Tester	0-700mmHg (resolution = accuracy = +-5mmHg)

13.0 TROUBLESHOOTING

Unit will not turn on	Replace battery
Display is dull	Replace battery Adjust internal contrast pot
Display is too dark	Adjust internal contrast pot
Unit rattles when shaken	Wedge battery in battery compartment to prevent movement.

Connector pinouts

Pin

1 - Waveform output - 1V ECG or IBP output
2 - Not connected
3 - Not connected
4 - Stimulator positive input (0-100mA range)
5 - Ground (IBP signal negative output)
6 - IBP signal positive output
7 - Stimulator negative input (0-100mA range)
8 - Excitation positive input
9 - Excitation negative input

WAVEFORMS

ECG standard

Time	Gradient	
25	- baseline	
50,	102	P-wave
20,	0	
50,	-102	
30,	0	
20,	-256	Q wave
20,	3100	R wave
20,	-3100	
20,	256	S wave
120,	0	
60,	130	
30,	0	
60,	-130	
0,	0	end of QRS complex

ECG fast:

25,	0
20,	2880
20,	-2880
80,	100
50,	0
80,	-100
0,	0